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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MITCHELL, TEENA KAY	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,112	HIPOLITO ET.AL.	
	Examiner	Art Unit	
	Teena Mitchell	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-18,20 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9-18,20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: The first lines of the specification note the instant application is a continuation of application 10/040,982; however, the current status of the parent application referenced should be included (i.e., U.S. Patent 6,668,832). Correction is required.

Claim Objections

Claim 14 is objected to because of the following informalities: Line 2, "...patent..." should be amended to read --patient--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The factual inquiries set forth in *Graham* v. *John De re Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. **Determining the scope and contents of the prior art.**
2. **Ascertaining the differences between the prior art and the claims at issue.**
3. **Resolving the level of ordinary skill in the pertinent art.**
4. **Considering objective evidence present in the application indicating obviousness or nonobviousness.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (4,774,943) in view of Sheridan (3,508,554).

Yu in an endotracheal tube discloses:

- A tubular member (1)
- Having a distal end (16) and a proximal end (8); and

- A plurality of visually distinct regions (6) at a proximal end of the tubular member (1), wherein each of the distinct regions comprises a respectively different color (Col. 4, lines 45-55 and Col. 5, lines 6-22).

The difference between Yu and claim 1 is the location of the distinct regions a first distinct region spaces about 6.5-7.0 cm from the distal end, a second distinct region spaced about 7.5-8.0 cm from the distal end, and a third distinct region spaced about 8.5-9.0 cm from the distal end.

Sheridan in an endotracheal tube teaches markings (10) provided to designate the distance from the distal end to aid the physician or surgeon in use of the tube, as will be understood by those skilled in the art, these distance markings will vary with the tube size (Col. 4, lines 62-73).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to locate the markings on the tube of Yu to employ any placement on the endotracheal tube based on the teachings of Sheridan that such is well-known in the art that the markings would vary based on the tube size and inasmuch as a neonate tube is a different size than a pediatric or adult tube, requiring placement of the markings at different locations on the tube based on the tube size. Therefore, one of ordinary skill in the art could arrive at the claimed locations of about 6.5-7.0 cm, 7.5-8.0 cm, and 8.5-9.0 cm, as disclosed by applicants own omission and the principle of neonate intubation on pages 7 and 8 of the instant application.

With respect to claim 2, Yu discloses an adapter coupled to the proximal end (8).

With respect to claim 4, Yu discloses wherein each of the plurality of distinct regions comprises a red or green color (Col. 5, lines 6-22).

With respect to claim 5, the tube of Yu is fully capable of being adapted for use with an infant or a premature infant because it is well known in the art that endotracheal tubes are used in pediatric care to supply oxygen/fluids.

With respect to claim 6, Yu does not give the length of the tube, however it is well-known in the art that the length of the tube is dependent on the intended use and the person it is to be used on (factoring size and age), as an infant would not require the same length of tube that an older person (i.e., teenager, adult) would require, therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the length of the tube being about 20cm.

With respect to claim 7, Yu does not disclose that insertion depth is dependent on patient's weights. However, by applicants own omission on pages 7 and 8 of the disclosure of the instant application with regard to the intubation depth dependent on the weight of an infant, it would have been obvious to one of ordinary skill in the art at the time the invention was made to locate the plurality of different colored lines representing a different endotracheal tube insertion depth for patients of different weights as depth of insertion of the tube of an baby/infant is dependent on the baby/infant weights.

With respect to claim 9, Yu does not disclose a fourth distinct region spaced about 9.5cm from the distal end. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tube of Yu to

employ a fourth distinct region as mere duplication of parts absent a new and unexpected result being produced. In re Harza, 274 D.2d 669, 124 USPQ 378 (CCPA 1960).

With respect to claim 10, note rejection of claim 1 above Yu/Sheridan with respect to location of the distinct regions on the tube.

With respect to claim 11, while Yu does not disclose a safety marking, by applicants own omission safety lines at the end of the endotracheal tube have become known as, "vocal cord localizers". Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a safety marking adapted for alignment adjacent to patient's vocal cords as safety markings at the distal end to the endotracheal tube is well-known in the art to control the depth of insertion of the endotracheal tube during the intubation process (note page 6 of the disclosure of the instant application).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 15-18, 20, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-13 of U.S. Patent No. 6,668,832. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 12 of the instant application, is broader in the aspect that the aligning step does not state, "with a fixed anatomical structure of the patient, wherein the patient has an upper gum, and wherein the fixed anatomical structure is the upper gum" and is therefore broader than the patented claim 9 and would be anticipated by the patented claim; claim 12 of the instant application also incorporates the limitations of claim 10 of the patent and one of ordinary skill in the art at the time the invention was made would have considered it obvious to incorporate the limitations of patented claim 10 into independent claim 12 of the instant application.

With respect to claim 15, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the visually distinct region prior to step b) because the visually distinct region allows the user to know how far the endotracheal tube is being inserted into the patient and selecting the visually distinct region prior to inserting allows for proper placement of the endotracheal tube into the patient and ensures the tube is not inserted too far based on the visually distinct region being selected prior of inserting the tube.

With respect to claim 16 of the instant application, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine a weight for the patient and using the determined weight for the patient to select the one visually

distinct region and doing these steps prior to the inserting step b). Based on applicants own omission on pages 7 and 8 of the disclosure of the instant application with regard to the intubation depth dependent on the weight of an infant, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine a weight for the patient and base on the patient's weight select the visual distinct region to ensure proper placement of the tube in the patient. It would have been obvious that obtaining the weight and then selecting the visually distinct regions would be done prior to inserting the distal end of the endotracheal tube into the patient because different visually distinct regions represent a different endotracheal insertion depth for patient's of different weights, as depth of insertion of the tube of a baby/infant is dependent on the baby/infant's weight (note applicant's disclosure pages 7 and 8) and such is well known in the respiratory art.

With respect to claim 17 of the instant application, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed endotracheal tube with an infant because it is well known in the respiratory art to use endotracheal tubes on infants for providing oxygen/gases/fluids.

With respect to claim 18 of the instant application, note rejection of claim 17 above.

With respect to claim 22 of the instant application, the claim is merely broader than patented claim 12 as the instant application claim does not have the limitation of, "wherein the endotracheal tube further comprises." Therefore the patented claim 12, "anticipates" the application claim.

Claims 13, 14, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 13 of U.S. Patent No. 6,668,832 in view of Yu (4,774,943).

With respect to claim 13 of the instant application, the limitations are more specific than claim 13 of the patent. The difference between claim 13 of the patent is the step of securing the endotracheal tube to the patient. Yu in an endotracheal tube with visual indicators (6) teaches securing the tube to a face of a patient providing flanges (3) to which adhesive tape can be attached providing an easier means for health care providers to secure the tube to a patient's face (Abstract). It would have been obvious to modify the tube of the patent with any well known securing means doing so would have provided a an easier means for health care providers to secure the tube to a patient's face including the flange and adhesive tape taught by Yu. One of ordinary skill in the art at the time the invention was made would have considered it obvious to secure the endotracheal tube to the patient after step c) because after aligning the tube it is well known that to ensure proper placement of the tube is maintained, the tube is secured to the patient thereby limiting any movement of the tube.

With respect to claim 14 of the instant application, note rejection of claim 13 above. As for the use of tape in the securing step, Yu teaches adhesive tape (10).

With respect to claim 20, Yu teaches visually distinct regions of red and green (Col. 5, lines 11-22).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show endotracheal tubes and securing devices: 6,561,192; 6,050,263; 5,868,132; 5,743,885; 5,626,565; 5,546,938; 4,142,527.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teena Mitchell
Examiner
Art Unit 3743
April 11, 2004